

FEB - 9 1999

K984610



1.0. 510K SUMMARY as required by: 807.92(c)

2.0 APPLICANT :

NAME M/s. SHIVA MEDICARE LIMITED
ADDRESS A 15, 16, 17(PART)
MADRAS EXPORT PROCESSINGZONE
KADAPERI, TAMBARAM,
CHENNAI 600 045.
INDIA.

PH.NO. : 91-44-2368011/ 2368322/2362656/2362657.

FAX NO : 91-44-2368327

EMAIL : shivam@md2.vsnl.net.in

CONTACT PERSON : MR. SATISH JAIN
EXECUTIVE DIRECTOR.

3. DEVICE TRADE NAME : NIL
COMMON NAME : Nitrile Examination Glove (Powder free)

4. Legally marketed device to which the company claiming equivalence:
Class I Nitrile Examination Gloves (Powder free) 80LZA that meets all the
requirements of ASTM D3578 - 95.

5. DESCRIPTION OF THE DEVICE :

Class I Nitrile Examination Gloves (Powder free) 80LZA that meets all
'the requirements of ASTM D3578- 95.

6. Intended use of the Device:

Nitrile examination glove (Powder free) is a Powder free devices made of Nitrile Latex
intended for medical purpose that is worn on the examiners hand or finger to prevent
contamination between patient and examiner.



Shiva Medicare Limited

(A 100% Export Oriented Unit)

Registered Office & Works : A 15-17, M.E.P.Z., Kadaperi, Tambaram, Chennai - 600 045 (INDIA)

Phones : 044/2368011/2368322 EMAIL: shivam@md2.vsnl-net.in Telefax : 091-44-2368327. Grams : "SHIVMEDI"

Corporate Office : 808, Pragati Tower, 26, Rajendra Place, New Delhi - 110 008 (INDIA)

Phones : 011/5762314/5767046, Telex : 031-65886 SHIVA IN Fax 011-5751700

7.0 TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE
COMAPARED TO PREDICATE DEVICE.

Measured Parameters of Nitrile Examination gloves (Powder free) manufactured by Shiva Medicare Ltd.,			ASTM D3578 Requirement for Nitrile Examination glove (Powder free)
Characteristics	SIZE	Value	
1. Length	EX-S	235-240 mm	220 mm minimum
	S	235-240 mm	220 mm minimum
	M	235-240 mm	230 mm minimum
	L	235-240 mm	230mm minimum
2. Width	EX S	70MM	70 +/- 6 mm
	S	82 mm	80 +/- 6 mm
	M	93 mm	95 +/- 6 mm
	L	107 mm	111 +/- 6mm
3. Thickness	EX S	0.10mm	0.08 mm minimum
	S	0.10mm	0.08 mm minimum
	M	0.10mm	0.08 mm minimum
	L	0.10mm	0.08 mm minimum

PHYSICAL PROPERTIES

CHARACTERISTICS	BEFORE AGEING		AFTER AGEING	
	SML VALUE *	ASTD 3578 REQUIREMENT	SML VALUE	ASTD 3578 Requirement
Tensile Strength	18 – 20 mpa	14 mpa min	16 – 18 mpa	14 mpa min
Elongation at break %	750 – 800%	700% min	650-700%	500% min

SML – SHIVA MEDICARE LIMITED



PERFORMANCE REQUIREMENT:

Characteristics	Related defects	Level followed By		AQL followed by SML	AQL Value as per ASTM D3578.
		SML	As per ASTM D3578		
Freedom from Holes	Holes	S4	S4	1.5	4
Dimension	Width , Length Thickness.	S2	S2	4	4
Physical Property	Tensile Strength, Elongation at Break.	S2	S2	4	4

POWDER CONTENT

SML VALUE	ASTM REQUIREMENT
Nil Powder	2 mg/glove max

PROTEIN CONTENT:

SML VALUE	FDA REQUIREMENT
30 +/- 10 ppm	Value not fixed.

MOISTURE CONTENT:

SML VALUE	FDA REQUIREMENT
0.8% max	No value fixed

BIOCOMPATABILITY:

SML GLOVE	FDA REQUIREMENT
Biologically Compatible	Biologically Compatible



8.0 Performance Data:

The performance test data of the Nitrile Examination Glove powder free manufactured by Shiva Medicare Limited is given below.

Measured Parameters of Nitrile Examination gloves (Powder free) manufactured by Shiva Medicare Ltd.,		
Characteristics	SIZE	Value
1. Length	EX-S	235-240 mm
	S	235-240 mm
	M	235-240 mm
	L	235-240 mm
2. Width	EX S	70MM
	S	82 mm
	M	93 mm
	L	107 mm
3. Thickness	EX S	0.10mm
	S	0.10mm
	M	0.10mm
	L	0.10mm

PHYSICAL PROPERTIES

CHARACTERISTICS	Before Ageing	AfterAgeing
Tensile Strength	18 – 20 mpa	16 – 18 mpa
Elongation at break %	750 – 800%	650-700%

INSPECTION LEVEL OF AQL:

Characteristics	Related defects	Level	AQL
Freedom from Holes	Holes	S4	1.5
Dimension	Width , Length Thickness.	S2	4
Physical Property	Tensile Strength, Elongation at Break.	S2	4



POWDER CONTENT : 1 +/- 1 mg per glove

PROTEIN CONTENT: 30 +/- 10 ppm

MOISTURE CONTENT: .0.8% max

BIOCOMPATABILITY: Biologically Compatible.

9. Clinical Data : NA

7. CONCLUSION OF PERFORMANCE TEST DATA:

The Nitrile Examination gloves Powder free manufactured by Shiva Medicare Limited

- Meet or exceed the ASTM D3578
- Meet FDA Pin hole Requirement.
- Meet labelling claim as shown by the data in 6

8. ANY OTHER INFORMATION:

Any other information required by FDA regarding product safety and effectiveness will be provided on request.





DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 9 1999

Shiva Medicare Ltd.
C/O Mr. James F. Logan
Medical Reports Exchange
314 North Hunter Street
Baltimore, Maryland 21202

Re: K984610
Trade Name: Powder-Free Nitrile Examination Gloves, Blue
Regulatory Class: I
Product Code: LZA
Dated: December 11, 1998
Received: December 29, 1998

Dear Mr. Logan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of

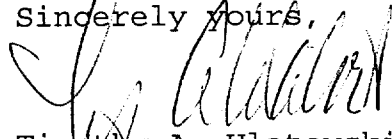
Page 2 - Mr. Logan

the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski
Director

Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3.0 INDICATIONS FOR USE:

APPLICANT : SHIVA MEDICARE LIMITED

510(K) No. : K984610

DEVICE NAME : NITRILE EXAMINATION GLOVES POWDER FREE, *Blue*

INDICATIONS FOR USE:

Nitrile Examination Gloves Powder free is a powder free disposable device made of Nitrile Latex intended for medical purpose, that is worn on the examiners hand or finger to prevent contamination between patient and Examiner.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use X

Chin S. Lim

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices

(Optional Format 1-2-96)

510(k) Number K984610